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# Regulatory Update: CMS Proposed Rule - Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2021

**August 24, 2020**

## Background & Summary

On Monday, August 3, the Centers for Medicare & Medicaid Services (CMS) issued the annual proposed rule to update the Calendar Year (CY) 2021 Medicare payment and policies for the Physician Fee Schedule (PFS). The Proposed Rule revises payment polices under the Medicare PFS and makes other policy changes, including proposals to both temporarily and permanently extend certain telehealth and supervision flexibilities provided during the COVID-19 Public Health Emergency (PHE). The PFS Addenda, along with supporting documents and tables referenced in the Proposed Rule, are available on the CMS website. The Proposed Rule also includes changes to the Quality Payment Program (QPP).

Comments are due **October 5, 2020**. Due to the PHE, CMS indicates there will likely be a 30-day delay in the publication of the final rule, with the effective date still scheduled for January 1, 2021. Vizient looks forward to working with members to help inform our comments to the agency.

## Calculation of the Proposed CY 2021 PFS Conversion Factor

There are three components of the PFS – work, practice expense (PE), and malpractice (MP) relative value units (RVUs). In order to calculate payments for each service, these three components are adjusted by geographic practice cost indices (GPCIs), which reflect variations in the costs of furnishing services compared to the national average costs for each component. Then, the relative value units (RVUs) are converted to dollar amounts via the application of a conversion factor (CF), which is calculated by CMS's Office of the Actuary (OACT). Finally, the Medicare PFS payment amount (based on the below formula) for a given service and fee schedule area is calculated based on the previously discussed metrics.

PFS Payment = [(Work RVU x Work GPCI) + (PE RVU x PE GPCI) + (MP RVU x MP GPCI)] x CF

For CY 2021, CMS proposes to decrease the CF by 10.61 percent to maintain budget neutrality. As described in the below table, the proposed 2021 CF is $32.26 (a significant decrease of $3.83 from the 2020 CF of $36.09).

| Calculation of the Proposed CY 2021 PFS Conversion Factor | | |
|---|---|---|
| **CY 2020 Conversion Factor** | | **36.0896** |
| Statutory Update Factor | 0.00 percent (1.0000) | |
| CY 2021 RVU Budget Neutrality Adjustment | -10.61 percent (0.8939) | |
| **CY 2021 Conversion Factor** | | **32.2605** |

## Determinations of Practice Expense Relative Value Units

The PE is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding MP expenses. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expenses and all other expenses.

In 2018, CMS finalized policy to update the PFS direct practice expense inputs (DPEI) for supply and equipment pricing, to be phased in over 4 years. For CY 2021, CMS received invoice submissions for approximately a dozen supply and equipment codes from stakeholders as part of the third year of the market-based supply and equipment pricing update. Based on this information and the agency's research, CMS proposes to update the prices of the supply and equipment items listed in Table 7 (pg. 57).

In the Proposed Rule, CMS indicates it is interested in refining the PE methodology and provides an update of efforts related to this refinement, including a technical expert panel (TEP) and the RAND Corporation's research regarding potential improvements to CMS's allocation methodology and related data. CMS believes that potential refinements could improve payment accuracy. The TEP report is available online and additional reports by RAND are available online (here and here). Notably, RAND's research found that physician-owned practices required 190 percent higher PE compared to facility-owned practices. In addition, RAND found that aggregating Medicare provider specialties into broader categories resulted in small specialty-level impacts relative to the current system. Based on these findings, there may be a need to update demographic information and specialty-specific inputs may not be required to accurately reflect resource costs. CMS is considering how to best incorporate market-based information into the PFS payment methodology, which could be similar to the market research CMS conducted to update supply and equipment pricing used to determine direct PE inputs.

CMS is also soliciting comment on how it might update the clinical labor data used for the direct PE inputs based on current salaries and compensation. Currently, CMS relies on data from the Bureau of Labor Statistics but seeks comment to determine the best data source. In addition, CMS may host a meeting with stakeholders as a step towards updating the PE methodology and related data. CMS welcomes feedback on RAND's reports but indicates it is not proposing changes at this time.

## Telehealth and Other Services Involving Communications Technology

Several conditions (e.g., patient eligibility, telehealth services, originating sites, distant site practitioners, interactive telecommunications system) must be met for Medicare to make payments for telehealth services under the PFS. Other services involving communications technology (e.g., remote evaluation of recorded video and/or images submitted by an established patient, brief communication technology-based service (CTBS), online assessment and management) are also covered under the PFS but are different from telehealth. During the PHE, CMS expanded access to both telehealth and CTBS, and in the Proposed Rule, CMS considers the scope of coverage for these services beyond the PHE, as described below.

### Medicare Telehealth Service List

CMS maintains a Medicare telehealth services list and has a long-standing process for adding or deleting services from the list.[1] Under this process, CMS receives requests from the public for adding services and assigns requests to one of two categories: Category 1 (services similar to professional consultations, office visits, and office psychiatry service currently on the Medicare telehealth services list) or Category 2 (services that are not similar to those currently on the Medicare telehealth services list and require additional evidence for telehealth reimbursement).

For CY 2021, CMS received requests and conducted an internal review to add services to the Medicare telehealth services list. In addition, in response to the PHE, CMS temporarily added numerous services to the list and assigned those services to Category 2. In the Proposed Rule, CMS considered which of those services (both those identified through CMS's traditional process and those added to Category 2 during the PHE) should be added to Category 1 of Medicare telehealth services list. The table below indicates the services CMS proposes to add to the Medicare telehealth services list on a Category 1 basis for CY 2021. Table 8 (pg. 82) of the Proposed Rule includes longer descriptions of each proposed Healthcare Common Procedure Coding System (HCPCS) code addition.

| CY 2021 Proposed Additions to the Medicare Telehealth Services List on a Category 1 Basis | |
|---|---|
| **HCPCS Code** | **Service Type** |
| GPC1X | Visit Complexity Associated with Certain Office/Outpatient E/Ms |
| 90853 | Prolonged Services |
| 96121 | Group Psychotherapy |
| 99XXX | Neurobehavioral Status Exam |
| 99483 | Care Planning for Patients with Cognitive Impairment |
| 99334 - 99335 | Domiciliary, Rest Home, or Custodial Care services |
| 99347 - 99348 | Home Visits |

[1] 1834(m)(4)(F)(ii) f the Act

CMS also proposes to create a third category of services ("Category 3") which describes services added to the Medicare telehealth list during the PHE that will remain on the list through the calendar year in which the PHE ends. The below table indicates the HCPCS codes and their service type that CMS proposes to add to the Medicare telehealth list on a Category 3 basis. Table 10 (pg.94) of the Proposed Rule includes longer descriptions of each proposed HCPCS code additions.

| Services Proposed for Temporary Addition to the Medicare Telehealth Services List on a Category 3 Basis | |
|---|---|
| **HCPCS Code** | **Service Type** |
| 99336 – 99337 | Domiciliary, Rest Home, or Custodial Care services, Established patient |
| 99349 – 99350 | Home visits, Established patient |
| 99281 – 99283 | Emergency Department Visits |
| 99315 – 99316 | Nursing facilities discharge day management |
| 99130 – 96133 | Psychological and Neuropsychological Testing |

In addition to the above noted changes, CMS requests comment on Medicare telehealth services that were added on an interim basis during the PHE (but not included in Category 3) that CMS is not proposing to retain after the PHE ends. Table 11 (pg. 98) provides information regarding telehealth services that are covered during the PHE but are not currently proposed to be covered temporarily (Category 3) or permanently (Category 1) after the PHE. CMS also seeks specific feedback on the following services which CMS did not propose to add to the Medicare telehealth services list on either a Category 1 or Category 3 basis:

- Initial and final discharge interactions (CPT codes 99234-99236 and 99238-99239)
- High level emergency department visits (CPT codes 99284-99285)
- Hospital, Intensive Care Unit, Emergency care, Observation stays (CPT codes 99217-99220; 99221-99226; 99484-99472, 99475-99476 and 99477-99480)

### Proposed Technical Amendment to Remove References to Specific Technology

Current regulations prohibit the use of telephones, facsimile machines, and electronic mail systems for purposes of furnishing Medicare telehealth services. During the PHE, through the March 31st COVID-19 Interim Final Rule (IFC), CMS provided additional flexibility regarding which technologies and technology requirements could be used to provide telehealth services. CMS is proposing to adopt these changes regarding specific technology and make technical amendments to remove outdated references to specific technology to provide more clarity regarding the agency's policy (e.g., use of telephones, such as a smartphone, may be permissible).

### Communication Technology-Based Services

In the CY 2019 PFS Final Rule and CY 2020 PFS Final Rule, CMS finalized separate payments for a number of communication technology-based services (CTBS) (reportable only by physicians and nonphysician practitioners (NPPs)), but that are not considered Medicare telehealth services. During the PHE, CMS indicated HCPCS

codes G2061-G2063 (online assessment by qualified NPP) could be billed by a range of practitioners (e.g., licensed clinical social workers and clinical psychologists, as well as physical therapists (PTs), occupational therapists (OTs), and speech-language pathologists (SLPs)) who bill Medicare directly and are operating within their scope of practice. CMS proposes to permanently adopt this policy and seeks comment on other practitioners who could provide these services.

CMS is also proposing to allow billing of other CTBS by certain NPPs, consistent with the scope of these practitioners' benefit categories, through the creation of two additional HCPCS G codes (G20X0: Remote assessment of recorded video and/or images submitted by an established patient and G20X2: Brief CTBS) that can be billed by practitioners who cannot independently bill for evaluation and management E/M services. CMS proposes to value these services to align with HCPCS codes G2010 (Remote evaluation of recorded video and/or images submitted by an established patient) and G2012 (Brief communication technology-based service), respectively.

To facilitate billing of the CTBS by therapists, CMS proposes to designate certain HCPCS codes (G20X0, G20X2, G2061, G2062, and G2063) as "sometimes therapy" services. When billed by a private practice PT, OT, or SLP, the codes would need to include the corresponding GO, GP, or GN therapy modifier to signify that the CTBS are furnished as therapy services furnished under the plan of care of an OT, PT, or SLP.

Lastly, CMS makes it clear that for all of the CTBS, consent from the patient to receive the services can be documented by auxiliary staff under general supervision, as well as by the billing practitioner. CMS also notes that while beneficiary consent is necessary (e.g., so the beneficiary is notified of cost sharing requirements), the agency does not believe the timing or manner in which consent is acquired should interfere with the provision of one of these services. CMS also proposes to retain the requirement that in instances when the brief CTBS originates from a related E/M service (including one furnished as a telehealth service) provided within the previous 7 days by the same physician or other qualified health care professional, this service would be considered bundled into that previous E/M service and would not be separately billable.

### Proposed Clarification of Existing PFS Policies for Telehealth Services

During the PHE, CMS received questions as to whether Medicare allows incident-to billing for telehealth services. Currently, CMS noted the existing definition of direct supervision requires on-site presence of the billing clinician when the service is provided. Consistent with policy CMS provided in the May 1st COVID-19 IFC, CMS proposes to clarify that services that are billed incident-to may be provided via telehealth incident-to a physicians' service and under the direct supervision of the billing professional. As a result, a physician can provide direct supervision without having to be on-site when care is provided incident-to the physician's service.

Also, consistent with the May 1st COVID-19 IFC, CMS clarifies that if audio/video technology is used in furnishing a service when the beneficiary and the practitioner

are in the same institutional or office setting, then the practitioner should bill for the service furnished as if it was furnished in person, and the service would not be subject to any of the telehealth requirements.

### Direct Supervision by Interactive Telecommunications Technology

During the PHE, CMS adopted an interim policy revising the definition of direct supervision to include virtual presence (excluding audio-only) of the supervising physician or practitioner using interactive audio/video real-time communications technology. CMS indicates it does not require real-time presence or observation of the service via interactive audio and video technology throughout the performance of the procedure. CMS proposes to extend this policy until the later of the end of the calendar year in which the PHE ends or December 31, 2021. However, CMS makes clear that this extended policy does not change the agency's requirements for "direct supervision" in the office setting (the physician or other supervising practitioner must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure).

CMS seeks comment as to whether there should be any additional "guardrails" or limitations to ensure patient safety/clinical appropriateness, beyond typical clinical standards, restrictions to prevent fraud or inappropriate use and information about implementation experiences.

### Comment Solicitation on Continuation of Payment for Audio-only Visits

During the PHE, CMS established payment for audio-only telephone E/M services (CPT codes 99441-99443). In addition, using the agency's emergency authority and authority provided for by the CARES Act, CMS separately issued a waiver of legal and regulatory requirements that telehealth services must be furnished using video technology. CMS is not proposing to continue recognizing these codes for payment under the PFS after conclusion of the PHE. Notably, CMS does not believe it can permanently waive the requirement that telehealth services be furnished using an interactive telecommunications system that includes two-way audio/video communication technology. In other words, CMS may lack authority to continue to allow audio-only telehealth services.

However, CMS recognizes the need for audio-only interaction and that this service could remain but would not be considered a "telehealth service". CMS seeks comment on:

- Whether it should develop coding and payment for a service like the virtual check-in but for a longer unit of time and with an accordingly higher value.
- The appropriate duration interval for such services and the resources in both work and PE that would be associated with furnishing them.
- Whether separate payment for such telephone-only services should be a provisional policy to remain in effect until a year or some other period after the end of the PHE or if it should be PFS payment policy permanently.

### Comment Solicitation on Coding and Payment for Virtual Services

In recent years, CMS began making separate payments for certain services that use telecommunications technology but are not considered Medicare telehealth services

(e.g., certain kinds of remote patient monitoring, a virtual check-in and a remote asynchronous service). CMS distinguishes these services from telehealth services because they are not the kind of services that are ordinarily furnished in-person but are routinely furnished using a telecommunication system. CMS seeks comment on the following for coding and payment for virtual services:

- Whether there are additional services that fall outside the scope of telehealth services where it would be helpful for CMS to clarify that they do not need to be on the Medicare telehealth services list in order to be billed (e.g., not inherently face-to-face and use telecommunications technology).
- Physicians' services that use evolving technologies to improve patient care that may not be fully recognized by current PFS coding and payment, including, for example, additional or more specific coding for care management services.
- Any impediments that contribute to health care provider burden and that may result in practitioners being reluctant to bill for CTBS.

### Comment Solicitation on PFS Payment for Specimen Collection for COVID-19 Tests

During the PHE, CMS has allowed physicians and NPPs to use CPT code 99211 to bill for services furnished incident-to their professional services, for both new and established patients, when clinical staff assess symptoms and collect specimens for purposes of COVID–19 testing. Typically, collection of a specimen via nasal swab or other method during the provision of a service might be reported as part of (bundled with) an office/outpatient E/M visit. CMS is soliciting public comment on whether it should extend or make permanent the policy to allow physicians and NPPs to use CPT code 99211 to bill for services furnished incident-to their professional services, for both new and established patients, when clinical staff assess symptoms and collect specimens for purposes of COVID–19 testing.

In addition, later in the Proposed Rule (pg. 367-368), CMS notes that during the PHE, the agency established that Medicare will pay a nominal specimen collection fee and associated travel allowance to independent laboratories for the collection of specimens for COVID–19 clinical diagnostic laboratory testing for homebound and non-hospital inpatients. To identify specimen collection for COVID-19, CMS established two new level II HCPCS codes (G2023 and G2024). CMS also seeks comment on whether these codes should be deleted when the PHE ends or whether this payment for COVID-19 tests might be needed following the PHE.

## Care Management Services and Remote Physiologic Monitoring Services

### Digitally Stored Data Services/ Remote Physiologic Monitoring/ Treatment Management Services

Remote Physiologic Monitoring (RPM) involves the collection and analysis of patient physiologic data that are used to develop and manage a treatment plan related to a chronic and/or acute health illness or condition. In recent years, CMS has finalized payment for seven CPT codes in the RPM code family. In the Proposed Rule, CMS provides clarification regarding several aspects of RPM, including that it considers RPM services to be E/M services and an established patient-physician relationship must already exist for RPM services to be covered by Medicare after the PHE.

During the PHE, CMS has provided flexibility to allow auxiliary personnel to provide certain RPM services (CPT codes 99453[2] and 99454[3]) under general supervision of the billing physician or practitioner. CMS proposes making this policy permanent. In addition, CMS proposes to continue to allow consent to be obtained at the time RPM services are furnished. CMS also clarifies that after the PHE, it will revert to previous policy which requires that 16 days of data be collected within 30 days to meet the requirements to bill CPT 99453 and 99454.

Lastly, CMS is seeking comment on whether the current RPM coding accurately and adequately describes the full range of clinical scenarios where RPM services may be of benefit to patients (e.g., shorter monitoring periods). CMS also welcomes comment on how RPM services are used in clinical practice, and how they might be coded, billed and valued under PFS.

### Transitional Care Management

In previous rulemaking, CMS identified 57 codes that could not be billed concurrently with Transitional Care Management (TCM) services because of potential duplication of services. In the CY 2020 PFS Final Rule, however, CMS finalized a policy to allow concurrent billing of TCM services with 16 of the previously prohibited 57 codes. In the Proposed Rule, CMS continues to refine this policy by proposing to allow concurrent billing of 14 HCPCS codes from the list of remaining HCPCS codes that cannot be billed concurrently with TCM. CMS also proposes to allow the new Chronic Care Management code (G2058) to be billed concurrently with TCM services when reasonable and necessary. The below table details the additional codes that could be billed concurrently with TCM.

| Additional Codes That Could Be Billed Concurrently with TCM | |
|---|---|
| **Code Family** | **CPT Code(s)** |
| End Stage Renal Disease Services (for ages less than 2 months through 20+ years) | 90951 |
| | 90954 – 90959 |
| | 90963 – 90969 |
| Complex Chronic Care Management Services | G2058 |

[2] CPT Code 99453: Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment
[3] CPT Code 99454: Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days

## Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the COVID-19 Pandemic

In the CY 2020 PFS Final Rule, for the office/outpatient E/M visit code set (CPT codes 99201 – 99215), CMS finalized a policy to generally adopt the new coding, prefatory language and interpretive guidance framework issued by the American Medical Association's (AMA's) CPT Editorial Panel. These changes, although finalized in the CY 2020 PFS Final Rule were set to go into effect on January 1, 2021. Under this framework, CPT code 99201 (Level 1 office/outpatient visit, new patient) would be deleted given its overlap with 99202 (Level 2 office/outpatient visit, new patient), since both are viewed as straightforward medical decision-making (MDM) and only differentiated by history and exam elements. As a result, under the new framework, the scope of the history and exam portion of the service (e.g., "problem-focused history and exam" and "expanded problem-focused history and exam) would no longer dictate the visit level for office/outpatient E/M visits. Rather, an office/outpatient E/M visit would include a medically appropriate history and exam, when performed. Code selection would be dependent on time or medical decision-making. Since publication of the CY 2020 final rule, CMS received additional stakeholder feedback which it addresses in the Proposed Rule.

In the CY 2020 PFS Final Rule, CMS adopted the AMA Relative Value Scale Update Committee (RUC)-recommended times (as listed in Column "CY 2021 Total Time (mins)" in the below table). However, CMS continued to consider the appropriate total time to adopt. For CY 2021, CMS proposes to adopt the actual total times rather than the total times recommended by the RUC for CPT code 99202– 99215. These proposed times are listed in the table below ("Proposed CY 2021 Total Time (mins)"). The below table provides a summary of the code, times and work RVUs finalized in the CY 2020 PFS Final Rule for CY 2021 and compares those time to proposed CY 2021 total times described by CMS in the Proposed Rule.

| Summary of Codes and Work RVUs Finalized in the CY 2020 PFS Final Rule for CY 2021 with Certain CY 2021 Proposals | | | | | |
|---|---|---|---|---|---|
| HCPCS Code | Current total time (mins) | Current Work RVU | CY 2021 Work RVU | CY 2021 Total Time (mins) | **Proposed** CY 2021 Total Time (mins) |
| 99201 | 17 | 0.48 | N/A | N/A | N/A |
| 99202 | 22 | 0.93 | 0.93 | 22 | 20 |
| 99203 | 29 | 1.42 | 1.6 | 40 | 35 |
| 99204 | 45 | 2.43 | 2.6 | 60 | 60 |
| 99205 | 67 | 3.17 | 3.5 | 85 | 88 |
| 99211 | 7 | 0.18 | 0.18 | 7 | 7 |
| 99212 | 16 | 0.48 | 0.7 | 18 | 16 |
| 99213 | 23 | 0.97 | 1.3 | 30 | 30 |
| 99214 | 40 | 1.5 | 1.92 | 49 | 47 |

| | | | | | |
|---|---|---|---|---|---|
| 99215 | 55 | 2.11 | 2.8 | 70 | 70 |
| 99XXX | N/A | N/A | 0.61 | 15 | - |
| GPC1X | N/A | N/A | 0.33 | 11 | - |

### Revaluing Services that are Analogous to Office/Outpatient E/M Visits

In the CY 2020 PFS proposed rule, CMS recognized that there are services for which the values are closely tied to the values of the office/outpatient E/M visit codes. In this Proposed Rule, CMS revalues certain services (e.g., End-Stage Renal Disease Monthly Capitation Payment Services; TCM services; maternity services; assessment and care planning for patient with cognitive impairment; Initial Preventive Physical Examination (IPPE) and Initial and Subsequent Annual Wellness (AWV) Visits; Emergency Department visits; therapy evaluations; behavioral healthcare services; and ophthalmological services) relative to the new office/outpatient E/M visit values.

For TCM services (CPT codes 99495 and 99496), in the CY 2020 PFS Final Rule, CMS finalized the RUC-recommended work and direct PE inputs for the TCM codes which resulted in small RVU increases for both codes. For CY 2021, CMS proposes to increase the work RVUs associated with the TCM codes based on the new valuations for the level 4 (CPT code 99214) and level 5 (CPT code 99215) office/outpatient E/M visits for established patients. Tables 19 and 20 (pgs. 161 and 165) include the current and proposed work RVUs, physician time and clinical staff time, for the TCM codes and other codes considered by CMS in the Proposed Rule.

Also, regarding prolonged office/outpatient E/M visits (CPT code 99XXX), CMS provides two tables on pages 180 and 181 of the Proposed Rule as examples to describe the agency's proposed prolonged office/outpatient E/M visits reporting for new and established patients.

CMS proposes new work RVUs for emergency department visits, therapy and psychotherapy services. Current and proposed work RVUs for the HCPCS codes for these services are provided in Table 21 (pg. 172).

In addition, CMS solicits comment on the HCPCS add-on code GPC1X which describes the "visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex condition." CMS requests more specific information regarding what aspects of the definition of HCPCS add-on code GPC1X are unclear, how they might address those concerns, and how they might refine our utilization assumptions for the code.

## Scope of Practice and Related Issues

In December 2019, CMS requested feedback to identify Medicare regulations which contain more restrictive supervision requirements than existing state scope of practice laws. In addition to the proposals noted below, CMS seeks information about the number and names of states that have licensure or scope of practice laws in place, as

well as any facility-specific policies, that would impact the ability of clinicians to exercise the flexibilities CMS proposes.

### Teaching Physician and Resident Moonlighting Policies

In the March 31st and May 1st COVID-19 IFCs, CMS temporarily implemented several policies related to PFS payments for teaching physicians' services involving residents and resident moonlighting regulations. CMS is considering whether the flexibilities[4] provided during the PHE should be extended on a temporary basis (e.g., until December 31, 2021) or be made permanent.

In the March 31st COVID-19 IFC, CMS temporarily allowed Medicare payment for teaching physician services when a resident furnishes Medicare telehealth services while a teaching physician is present using audio/video real-time communications technology. CMS is considering whether this policy should be extended on a temporary basis (e.g., until December 31, 2021) or be made permanent and seeks comment.

Also in the March 31st COVID-19 IFC, CMS temporarily allowed medical residents to provide care not related to their approved Graduate Medical Education (GME) programs to inpatients at their training program's hospital as separately billable physicians' services provided certain conditions are met (e.g., identifiable physicians' services, meet certain conditions for payment, resident is fully licensed by the state in which the services are performed, and the services can be separately identified from those services that are required as part of the approved GME program). CMS is considering whether this policy should be extended on a temporary basis (e.g., until December 31, 2021) or be made permanent and seeks comment.

### Primary Care Exception Policies

Under the "primary care exception," reimbursement of lower and mid-level complexity services can be provided when a medical resident provides these services without the physical presence of a teaching physician. In the March 31st COVID-19 IFC, CMS temporarily allowed all levels of office/outpatient E/M visits to be furnished by the resident and billed by the teaching physician under the primary care exception. In the May 1st COVID-19 IFC, CMS further expanded the list of services included in the primary care exception and allowed PFS payment to the teaching physician for services furnished by residents via telehealth if the services were also on the list of Medicare telehealth services. CMS is considering whether this policy should be extended on a temporary basis (e.g., until December 31, 2021) or be made permanent and seeks comment.

[4] Flexibilities in which CMS is proposing extending or being made permanent are under §§415.172, 415.174, 415.18 and 415.184.

### Supervision of Diagnostic Tests by Certain Nonphysician Practitioners

In the May 1st COVID-19 IFC, CMS established a temporary policy to permit physician assistants (PAs), nurse practitioners (NPs) and certain other NPPs to supervise diagnostic tests. Prior to the PHE, only physicians were permitted to supervise diagnostic tests. CMS proposes to allow NPs, clinical nurse specialists (CNSs), PAs or certified nurse-midwives (CNMs) to supervise diagnostic tests on a permanent basis as allowed by state law and scope of practice laws. CMS is also proposing to make permanent a policy that supervision of diagnostic psychological and neuropsychological testing services can be done by NPs, CNS's, PAs or CNMs (in accordance with state rules), in addition to physicians and CPs who are currently authorized to supervise these tests.

### Pharmacists Providing Services Incident to Physicians' Services

In the Proposed Rule, CMS clarifies pharmacists may provide services incident-to the services of the billing physician or NPP (assuming with the appropriate level of supervision is provided and services are within the pharmacists scope of practice), if payment for the services is not made under the Medicare Part D benefit.

## Modifications Related to Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs

In the CY 2020 PFS Final Rule, CMS implemented coverage requirements and established new codes describing the bundled payments for episodes of care for the treatment of opioid use disorders (OUDs) furnished by opioid treatment programs (OTPs). For CY 2021, CMS proposes to extend the definition of OUD treatment services to include opioid antagonist medications, such as naloxone, for emergency treatment of opioid overdose. Under this proposal, beneficiaries receiving OUD treatment services from the OTP would be able to receive naloxone from the OTP under the OUD treatment services benefit, to the extent it is medically reasonable and necessary as part of their OUD treatment. CMS proposes two add-on G-codes (GOTP1 and GOTP2) and Table 30 (pg. 349) provides descriptions and proposed approximate payment amounts for nasal naloxone and auto-injector naloxone. CMS welcomes comment on this proposal, the need for an add-on payment for injectable naloxone and whether payment for providing overdose education to the beneficiary or their family member should be included in the current bundled payment or if CMS should consider establishing an add-on payment.

CMS also proposes to modify the payment methodology for the drug component of the bundled payment rates for OUD services in order to limit wholesale acquisition cost (WAC)-based payments. In addition, CMS proposes to use WAC pricing to determine the payment rate for the add-on code for the auto-injector naloxone.

In addition, CMS proposes changes to billing and payment policies related to institutional claim forms, periodic assessments, date of service, coding and annual updates. The list of the payment rates for OUD treatment services furnished by OTPs, with the annual update applied for CY 2021, is available in the file called CY 2021 OTP Proposed Payment Rates on the CMS Web site under downloads.

## Medical Records Documentation

In the CY 2020 PFS Final Rule, and similarly expressed in the May 1st COVID-19 IFC, any individual who is authorized under Medicare law to furnish and bill for their professional services may review and verify (sign and date) the medical record for the services they bill, rather than re-document, notes in the medical record made by physicians, residents, nurses, and students (including students in therapy or other clinical disciplines), or other members of the medical team. In the Proposed Rule, CMS clarifies that the broad policy principle that allows billing clinicians to review and verify documentation added to the medical record for their services by other members of the medical team also applies to therapists.

## Comprehensive Screenings for Seniors: Section 2002 of the Substance Use-Disorder Prevention that Promote Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)

Section 2002 of the SUPPORT Act, Comprehensive Screening for Seniors, required the Initial Preventive Physical Examination (IPPE) and Annual Wellness Visit (AWV) to include screening for potential substance use disorders (SUDs) and a review of any current opioid prescriptions. CMS proposes several regulatory changes, including adding the terms “screening for potential substance use disorders” and “a review of any current opioid prescriptions” (and defines this term), and revising the “Initial Preventive Physical Examination”, “first annual wellness visit providing personalized prevention plan services” and “subsequent annual wellness visit providing personalized prevention plan services”.

## Proposal to Remove Selected National Coverage Determinations (NCD)

CMS proposes to continue to use the criterion established in 2013 to regularly identify and remove national coverage determinations (NCDs) that no longer contain clinically pertinent and current information. Eliminating an NCD for items and services that were previously covered means that the item or service will no longer be automatically covered by Medicare. Alternatively, if the previous NCD barred coverage for an item or service, then a Medicare Administrative Contractor (MAC) could not cover the item or service. According to CMS, it has been five years since the agency last evaluated older NCDs for removal. Table 37 (pg. 527) lists the nine NCDs CMS proposes to remove. CMS seeks comments on this proposal and recommendations for NCDs for CMS to consider for future rulemaking.

## Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan

Since 2003, electronic prescribing (e-prescribing) has been optional for physicians and pharmacies for prescriptions made for covered Part D drugs. In a recent proposed rule, CMS proposed to require e-prescribing for controlled substances for covered Part D drugs under a prescription drug plan or MA-PD plan. During the PHE, e-prescribing has become more commonplace, and CMS seeks feedback from

prescribers regarding their experiences, including challenges or circumstances where e-prescribing could not occur. In the Proposed Rule, CMS also proposes to require that all prescribers conduct e-prescribing of schedule II-V controlled substances using the NCPDP SCRIPT 2017071 standard by January 1, 2022, except in circumstances where the Secretary waives the requirement. CMS believes requiring e-prescribing would uniquely affect physicians and welcomes comments, particularly considering the feasibility for prescribers to meet the proposed January 1, 2022 deadline, on the impact of the proposal on overall interoperability rule and the impact on medical record systems.

## Updates to Certified Electronic Health Record Technology due to the 21st Century Cures Act Final Rule

As authorized under law, CMS makes incentive payments to eligible professionals, eligible hospitals, critical access hospitals (CAHs) and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of Certified Electronic Health Record Technology (CEHRT). The 21st Century Cures Act final rule[5] finalized updates to the 2015 Edition of health IT certification criteria. CMS proposes that healthcare providers participating in the Promoting Interoperability Programs or Quality Payment Program (QPP) would be required to use only technology that is considered certified under the ONC Health IT Certification Program according to the timelines finalized in the Cures Act final rule (including enforcement discretion period provided in response to the PHE). As a result, program participants have until August 2, 2022 to use technology certified to either version as that technology will still be considered certified under the ONC Health IT Certification Program.

CMS also notes two instances in which the updates to the 21st Century Cures Act final rule will affect specific Promoting Interoperability objectives and measures. The changes are the retiring of the "drug formulary and preferred drug list checks" and the new API certification criterion, "standardization API for patient and population services". Table 38 (pg. 574) provides additional information on the Medicare Promoting Interoperability Objectives and Measures, and 2015 Edition Certification Criteria. CMS seeks comment on these proposals.

## Proposed Changes to Certification Requirements under the Hospital Inpatient Quality Reporting (IQR) Program due to the 21st Century Cures Act

For each Hospital IQR Program payment determination, CMS requires that hospitals submit data on each specified measure in accordance with the measure's specifications for a particular period. In the 21st Century Cures Act final rule, ONC finalized updates to the existing 2015 Edition criteria and introduced new 2015 Edition criteria. Health IT developers have until August 2, 2022 to make technology available that is certified to the updated and/or new criteria. For the Hospital IQR Program

[5] 85 FR 25642 through 25961

beginning with the CY 2020 reporting period/FY 2023 payment determination and for subsequent years, CMS proposes to provide flexibility for hospitals. Specifically, CMS proposes to allow hospitals to use either: (1) technology certified to the 2015 Edition criteria for CEHRT as was previously finalized in the FY 2019 IPPS/LTCH final rule, or (2) technology certified to the 2015 Edition Cures Update standards as finalized in the 21st Century Cures Act final rule. CMS seeks comment on this proposal.

## CY 2021 Updates to the Quality Payment Program

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Quality Payment Program (QPP) for eligible clinicians. Under the QPP, eligible clinicians can participate via one of two tracks – the Merit-based Incentive Payment System (MIPS) or the Advanced Alternative Payment Models (Advanced APMs). CMS began implementing the QPP through rulemaking for CY 2017. CMS notes in a related QPP Fact Sheet that it limited the number of significant changes to the QPP in 2021 as a result of the PHE, and provides a table comparing CY 2020 policies with CY 2021 proposals. Generally, the proposed updates to the QPP are effective January 1, 2021 (the 2021 performance period/2023 payment year).

### Major MIPS Proposals

In the CY 2020 PFS final rule, CMS finalized a definition of a MIPS Value Pathway (MVP) as a subset of measures and activities established through rulemaking. CMS proposes polices related to developing an MVP; proposes a new APM Performance Pathway (APP) to replace the APM scoring standard; updates the MIPS performance measures and activities; updates cost and quality category weights; and updates scoring policies.

#### Participation Pathways

For MVPs, CMS is not proposing any MVP candidates and, as a result, MVPs will not be available for MIPS reporting until the 2022 performance period, or later. CMS also proposes adding more detail to the MVP guiding principles. In addition, CMS proposes new development criteria and a process for candidate MVP collaboration, solicitation, and evaluation.

CMS proposes the new APP that is complementary to the MVPs, available only to participants in MIPS APMs, and would effectively replace the MIPS APM scoring standard (CMS proposes to sunset it in the Proposed Rule). It would also be required for Medicare Shared Savings Program (MSSP) quality determinations for ACOs. CMS proposes the APP would have a fixed set of measures for each performance category and the following weights: Quality (50 percent), Cost (0 percent), Promoting Interoperability (30 percent) and Improvement Activities (20 percent). For final scoring, CMS would score each performance category and multiply each performance category score by the applicable performance category weight, and then calculate the sum of each weighted performance category score and apply any applicable adjustments.

## MIPS Performance Category Measures and Activities

CMS proposes the following performance category weights for the 2021 performance period: Quality (40 percent, a 5 percent decrease from CY 2020); Cost (20 percent, a 5 percent increase from CY 2020); Promoting Interoperability (25 percent, no change from CY 2020); and Improvement Activities (15 percent, no change from CY 2020). CMS proposes the performance threshold to be 50 points (a decrease of 10 points from CY 2020). By law, for the 2022 performance period, the Cost and Quality performance categories must be equally weighted at 30 percent.

CMS also proposes changes to the MIPS quality measure set as described in Appendix 1 (starting on pg. 1037), including the addition of new measures, updates to specialty sets, removal of existing measures, and substantive changes to existing measures. For future rulemaking, CMS notes it will consider changes being implemented under the 21st Century Cures Act (e.g., information blocking, prescription drug monitoring program (PDMP) growth, use of the United States Core Data for Interoperability set and Fast Healthcare Interoperability Resources specifications, and updates to the 2015 Edition health IT certification criteria and the ONC Health IT Certification Program).

For the Quality performance category, CMS proposes several changes. For example, due to the PHE, CMS proposes to use performance period (not historical) benchmarks to score quality measures for the CY 2021 performance period. CMS also proposes to sunset the CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians starting with the 2021 performance period.

For the Cost performance category, CMS proposes to update existing measure specifications to include telehealth services that are directly applicable to existing episode-based cost measures and the Total Per Capita Cost (TPCC) measure.

For the Improvement Activities performance category, CMS proposes changes to the Annual Call for Activities (e.g., an exception to the nomination period during the PHE; new criterion for new improvement activity nominations), a process for HHS-nominated improvement activities, and to modify two existing improvement activities.

For the Promoting Interoperability performance category measures, CMS proposes to increase the amount of the bonus points for the Query of PDMP measure from 5 points to 10 points. In addition, CMS proposes adding an optional Health Information Exchange (HIE) bi-directional exchange measure and established a high-performance standard for sharing information with other clinicians. The below table shows the proposed scoring methodology for the Performance Period in CY 2021.

| Objective | Measure | Maximum Points |
|---|---|---|
| Electronic Prescribing | e-Prescribing | 10 points |
| | *Bonus:* Query of PDMP | 10 points (bonus) |
| Health Information Exchange OR | Support Electronic Referral Loops by Sending Health Information | 20 points |
| | Support Electronic Referral Loops by Receiving and Reconciling Health | 20 points |

| | | |
|---|---|---|
| | Information (note: this measure has a proposed name change) | |
| Health Information Exchange (alternative) | HIE Bi-Directional Exchange | 40 points |
| Provider to Patient Exchange | Provide Patients Electronic Access to Their Health Information | 40 points |
| Public Health and Clinical Data Exchange | Report to two different public health agencies or clinical data registries for any of the following:<br>- Syndromic surveillance reporting<br>- Immunization registry reporting<br>- Electronic case reporting<br>- Public health registry reporting<br>- Clinical data registry reporting | 10 points |

### Advanced Alternative Payment Models

In the Proposed Rule, CMS clarifies its policies on Advanced Alternative Payment Models (APMs) determinations and Qualifying APM Participant (QP) determinations based on the anticipated questions stemming from the PHE. Since the CY 2017 QPP final rule, the QP determination at the APM Entity level (which relies on a scoring methodology) generally applies to all individual eligible clinicians who are on the Participation List of the Advanced APM. The QP determination Threshold Score calculations are aggregated using data for all eligible clinicians participating in the APM Entity on each snapshot date (March 31, June 30, August 31) during the QP Performance Period. If the QP threshold is met, all individual eligible clinicians in that APM Entity would receive the same QP determination, applied at the National Provider Identifier (NPI) level, for the relevant performance year. Beginning in the 2021 QP Performance Period, CMS proposes changes to how it calculates QP Threshold Scores, such that prospectively attributed Medicare patients would be removed from the denominators when calculating QP Threshold Scores for APM Entities or certain individual eligible clinician in Advanced APMs. CMS believes this policy will help prevent dilution of the QP Threshold Score for the APM Entity of individual clinical in an Advanced APM that uses retrospective alignment.

CMS also proposes a targeted review process through which an eligible clinician or APM Entity may request review of a QP or Partial QP determination if they believe that, due to a CMS clerical error, an eligible clinician was omitted from a Participation List used for purposes of QP determinations.

### Medicare Shared Savings Program

The Medicare Shared Savings Program (MSSP) serves as a mechanism for eligible groups of providers and suppliers that participate in an Accountable Care Organization (ACO) to continue to receive traditional Medicare FFS payments and a shared savings payment if the ACO meets specified quality and savings requirements.

During the PHE, CMS made modifications to the Shared Savings Program's extreme and uncontrollable circumstances policy to offer reporting relief to ACOs. Since CMS anticipates the reporting flexibilities provided during the PHE will have broader implications, CMS proposes to modify measurement of ACO quality performance under the Shared Savings Program, update the definition of primary care services used in beneficiary assignment, and revise the policy for determining the amount of repayment mechanism arrangements for certain ACOs continuing their participation under a two-sided model.

In addition, due to the PHE, for performance year 2020 only, CMS proposes to waive the requirement for ACOs to field a Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey. ACOs would receive automatic full credit for the patient experience of care measures. CMS seeks comment on this proposal.

For performance year 2021, CMS proposes that ACOs participating in the MSSP would be required to report quality measure data via the APP, instead of the CMS web interface. Under this approach, the total number of measures in the ACO quality measure set would be reduced from 10 to 3. Under the proposed redesign, ACOs would be required to receive a higher Quality performance score equivalent to or above the 40th percentile across all MIPS Quality performance category scores in order to share in savings or avoid owing maximum losses. If the Quality performance standard is met, the ACO would receive the maximum sharing rate. Alternatively, if the Quality performance standard is not met, the ACO would not be eligible to share in any earned savings. For ACOs that owe shared losses, the losses would be scaled using the MIPS Quality performance category score under Track 2 and the ENHANCED track; and under the BASIC track and the Track 1+ ACO Model, CMS would continue to apply a fixed 30% loss sharing rate.

## What's Next?

Although CMS typically publishes the final PFS/QPP regulation in early November, stakeholders should anticipate the final rule release in late November or December 1. CMS has indicated the rule may have a 30-day effective date and the proposals are effective at the beginning of the following calendar year (January 1, 2021). The comment period closes on October 5, 2020.

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this proposed rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. Please direct your feedback to Jenna Stern, Sr. Regulatory Affairs and Public Policy Director in Vizient's Washington, D.C. office.